

Amendments to Specification

Please amend the specification at page 23, lines 16-27 in the following manner:

Furthermore, it is also advantageous to add compounds to CLA preparations to decrease oxidation during storage. Compounds that prevent oxidation (antioxidants) have two general mechanisms of action. The first is the prevention of oxidation by lipid peroxide radical scavenging. Examples include but are not limited to tocopherols and ascorbylpalmitate. The second mechanism for preventing oxidation is by the chelation of metal ions. Examples of metal oxidant chelators include, but are not limited to, citric acid esters and lecithin. Some commercially available compounds (*e.g.*, CONTROX®, Grunau (Henkel), Illertissen, DE) include both peroxide scavengers and metal chelators (*e.g.*, lecithin, tocopherols, ascorbylpalmitate, and citric acid esters). In some embodiment of the present invention, metal oxidant chelators are added to CLA containing compounds to prevent oxidation. In other embodiments, a combination of metal oxidant chelators and peroxide scavengers is included in the CLA composition.

Please amend the specification at page 25, line 21 to page 26, line 2 in the following manner:

An example illustrating OSI measurement of CLA in the presence or absence of antioxidants is given in Example 15. In Example 15, a triacylglyceride of CLA is prepared by the method of Example 14. Samples are placed in open dishes with varying amounts (0-0.1%) of four antioxidants ~~compositions: Controx~~ CONTROX® (Grunau (Henkel), Illertissen, DE), ~~Herbalox~~ HERBALOX® (an extract of rosemary; Kalsec, Kalamazoo, MI), ~~Covi-OX~~ COVIOX® (Grunau (Henkel), Illertissen, DE), and alpha-tocopherol). The OSI is calculated as described above. Results are shown in Table 29 and Figure 2. The addition of alpha-tocopherol did not significantly increase the OSI value. ~~Herbalox~~ The HERBALOX® composition increased the value by approximately 2-3 fold. ~~Covi-OX~~ The COVIOX® and ~~Controx~~ CONTROX® compositions increased the OSI values by a greater amount, approximately 4 and 6 fold, respectively. This experiment demonstrated that the addition of antioxidants can slow the oxidation of CLA containing compounds during storage.

Please amend the specification at page 26, lines 5-21 in the following manner:

The conjugated linoleic moieties of the present invention may be provided in a variety of forms. In some embodiments, administration is oral. The CLA moieties may be formulated with suitable carriers such as starch, sucrose or lactose in tablets, pills, dragees, capsules, solutions, liquids, slurries, suspensions and emulsions. Preferably, the CLA formulations contain antioxidants, including, but not limited to ~~Controx, Covi-OX~~, **CONTROX®** and **COVLOX®** compositions, lecithin, and oil soluble forms of vitamin C (ascorbyl palmitate). The CLA may be provided in aqueous solution, oily solution, or in any of the other forms discussed above. The tablet or capsule of the present invention may be coated with an enteric coating which dissolves at a pH of about 6.0 to 7.0. A suitable enteric coating which dissolves in the small intestine but not in the stomach is cellulose acetate phthalate. In some embodiments, the CLA is provided as soft gelatin capsules containing 750 mg 80% CLA (~~Tonatin~~ **TONALIN®**). The CLA may also be provided by any of a number of other routes, including, but not limited to, intravenous, intramuscular, intra-arterial, intramedullary, intrathecal, intraventricular, transdermal, subcutaneous, intraperitoneal, intranasal, enteral, topical, sublingual or rectal means. Further details on techniques for formulation for and administration and administration may be found in the latest edition of *Remington's Pharmaceutical Sciences* (Maack Publishing Co., Easton, PA).

Please amend the specification at page 57, line 24 – page 58, line 2 in the following manner:

This example demonstrates the oxidation of CLA over time. CLA was prepared as described in Example 11. One sample was left in a test tube at room temperature for 21 days. A second reference sample was stored at -30°C. The increase in pentane and hexane in both samples was measured by the method described in Example 12. Results are shown in Table 26 28. The amount of both pentane and hexane present in the sample increased by approximately two-fold after 21 days of storage at room temperature. This example demonstrated that CLA samples prepared by chemical conjugation of oils oxidize over time to form undesirable volatile organic compounds.

Please amend the specification at page 58, lines 15 -19 in the following manner:

Aliquots of the product of Example 14 were placed in open dishes and stored under controlled conditions at 60°C. Antioxidants were added to some of the samples in varying

amounts. Antioxidants used were ~~CONTROX®~~ ~~Controx~~ (Grunau (Henkel), Illertissen, DE), ~~Herbalox~~ ~~HERBALOX®~~ (Kalsec, Kalamazoo, MI), and ~~Covi-OX~~ ~~COVLOX®~~ (Grunau (Henkel), Illertissen, DE) compositions, and alpha-tocopherol. Antioxidants were added at 0, 0.02, 0.05, and 0.10 % by weight.

Please amend the specification at page 58, line 20 – page 59, line 2 in the following manner:

The oxygen stability index (OSI) was measured using a method known in the art (AOCS official method Cd 12b-92 using an OSI apparatus from Omnion Instruments). Samples (5 g) were held in a thermostable bath and a stream of purified air was passed through the samples. The effluent air from the samples was bubbled through a vessel containing deionized water. The conductivity of the water is continually monitored over time. The OSI (the point of maximum change of the rate of oxidation) is determined mathematically. Results of the OSI measurements are shown in Table 29 28 and Figure 2. The addition of alpha-tocopherol did not significantly increase the OSI value. ~~Herbalox~~ The HERBALOX® composition increased the value by approximately 2-3 fold. The COVLOX® ~~Covi-OX~~ and ~~Controx~~ CONTROX® compositions increased the OSI values by a greater amount, approximately 4 and 6 fold, respectively. This experiment demonstrated that the addition of certain antioxidants containing metal oxidant chelators can slow the oxidation of CLA containing compounds during storage.